

### REMARKS

Claims 7, 8, 14, 15, and 22-26 remain active in this application.

Applicants wish to thank Examiner Afremova for the helpful and courteous discussion with the Applicants' undersigned representative on October 22, 2003. During this discussion, various amendments and arguments were discussed to address the rejections under 35 U.S.C. §112 and 35 U.S.C. §103. The present response is believed to reflect and expand upon the content of this discussion. Reconsideration is respectfully requested.

The rejection of Claims 7, 8, and 22-26 under 35 U.S.C. §103(a) in view of WO 95/28853 (Muller et al) in view of U.S. Patent No. 4,808,419 (Hsu); the rejection of Claims 7, 8, and 22-26 under 35 U.S.C. §103(a) in view of U.S. Patent No. 6,045,819 (Takebe et al) in view of Hsu; and the rejection of Claims 7, 8, 14, 15, and 22-26 under 35 U.S.C. §103(a) over Takebe et al and Muller et al in view of U.S. Patent No. 5,888,561 (Niederberger et al) and Hsu are respectfully traversed.

The present claims relate to method for producing hydrolyzed protein by subjecting a vegetable protein material containing saccharides to enzymatic hydrolysis, comprising:

- (1) conducting cultivation of a koji mold in a submerged culture fermenter-type reaction vessel to obtain a fungal culture;
- (2) mixing a dispersion of said vegetable protein material with said fungal culture to obtain a mixture; and
- (3) subjecting said mixture to enzymatic hydrolysis first at a temperature ranging from 15 °C to 39 °C with aeration and agitation and then at a temperature ranging from 41 °C to 50 °C,

to obtain said hydrolyzed protein,

wherein a ratio of reducing sugars present in said hydrolyzed protein obtained is 5 % by weight or less based on the total solid content in said hydrolyzed protein, and

wherein the temperature is shifted from a temperature ranging from 15 °C to 39 °C to a temperature ranging from 41 °C to 50 °C when from 10% to 60% of the total period of time required for completion of the enzymatic hydrolysis has passed; and

wherein *the sample in each of (1) to (3) are in a liquid state.*

Applicants have discovered that the presently claimed methods are unexpectedly effective for producing a protein hydrolyzate which is not browned and which resists browning for a prolonged period of time (see Declaration under 37 C.F.R. §1.132 by Toshimasa Ishii filed April 21, 2003, referred to herein as “the Ishii Declaration”).

The cited references contain no disclosure, which would suggest the presently claimed methods or the advantages afforded thereby. In particular, *none of the art of record discloses or suggests that each of (1) to (3) is in a liquid state.* Applicants note that the methods disclosed by Muller et al (bread cubes; solid), Hsu (malt-yeast extract agar; semi-solid), Takebe et al (a pulse crop; solid), and Niederberger et al (wheat gluten cubes; solid) utilize solid-state cultures and/or semi solid-state cultures.

Citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), MPEP §2143.03 states: “To establish a prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” Applicants submit that the disclosures of Muller et al, Hsu, Takebe et al, and Niederberger et al, in any combination, fail to meet this requirement, and as such the artisan would have no direction to practice the claimed method, much less the advantageous properties flowing therefrom. Accordingly, the present invention would not be obvious in view of the disclosures of Muller et al, Hsu,

Takebe et al, and Niederberger et al, in any combination. Accordingly, these references cannot affect the patentability of the present claims.

With respect to Muller et al, Applicants first note that the koji employed in Example 1 is obtained from bread cubes (a solid), which is certainly different from the claimed "liquid state." However, Applicants wish to make the following additional comments regarding the disclosure of Muller et al.

In the present invention, prior to hydrolysis of wheat gluten, liquid koji is produced. The liquid koji obtained thereby has a high protease activity that is estimated to be 304 units/ml. Hydrolysis of wheat gluten is then conducted by the liquid koji. Since the protease activity of the liquid koji is so high, protein hydrolysis begins immediately after addition of the liquid koji culture. As such, a remarkably short protein hydrolysis period is attained (approximately 8-24 hours).

Concurrent with protein hydrolysis, starch trapped in "gluten" is released into the broth (gluten consists of 80% protein, 10% starch, and 7-8% water). *Aspergillus oryzae* slowly converts the starch into glucose, which is then consumed by the *Aspergillus oryzae* leading to a reduction in the amount of residual glucose. This phenomenon is clearly shown in the Ishii Declaration filed on April 21, 2003.

In contrast, in Example 1 of Muller et al, fermentation is conducted in approximately 1-2 weeks, which is significantly longer than in the present invention. This increased fermentation period appears to be a result of the reduced quantity of *Aspergillus oryzae* employed in the fermentation broth. As a consequence thereof, the period of time required for protein hydrolysis increases arising from the reduction in the amount of enzymes responsible for catalyzing this reaction.

Moreover, in Muller et al the fermentation temperature is retained at 40-45°C, during

which protein hydrolysis proceeds. This high temperature provides an additional disadvantage as the enzymes involved in glycolysis are adversely affected by the increased heat of reaction, thereby resulting in an increase in the amount of residual glucose in the culture.

In view of the foregoing, Applicants submit that the obviousness rejections over the disclosures of Muller et al, Hsu, Takebe et al, and Niederberger et al (in any combination) are not longer tenable. Applicants request withdrawal of these grounds of rejection.

The rejection of Claims 7, 8, 14, 15, and 22-26 under 35 U.S.C. §112, second paragraph, has been obviated in part by appropriate amendment and traversed in part.

The Examiner remains concerned that the terms “completion” and “completed” are indefinite, Applicants respectfully disagree. Again, the Examiner’s attention is directed to MPEP §2173.02, which states:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Applicants note that the artisan would readily understand the meanings of these terms, as the Oxford American Dictionary (©1990) the term “complete” is defined as: 1) having all its parts, not lacking anything, 2) finished, *the work is now complete*. Thus, minimally, (C) above is satisfied. Therefore, by its very definition this term is *definite*.

Moreover, Applicants note that (A) is also satisfied by reference to the disclosure at page 19, line 19 to page 20, line 25 of the present specification. This disclosure clearly provides the necessary clarity to permit the artisan to readily understand the meaning of the

phrase “completion of enzymatic hydrolysis” by providing the artisan with a detailed summary of how a determination may be made of point that the hydrolysis reaction is complete and, thus, when the claimed percentage of completion is achieved to effectuate temperature shifting. Again, based on this disclosure, the aforementioned phrase is *definite*.

In view of the foregoing, Applicants believe that the language of the claims are such that a person of ordinary skill in the art could interpret the metes and bound of the claims so as to understand how to avoid infringement (MPEP §2173.02). Applicants note that this rejection appears to be because the Examiner merely wants the Applicant to improve the clarity or precision of the language used. However, since the skilled artisan can readily appreciate the meaning of the claims, Applicants submit that further amendments are not necessary.

Therefore, Applicants request withdrawal of the claim objections pursuant to MPEP §2173.02.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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